

### **REMARKS**

Claims 1-32 were presented for examination and were rejected. Claims 5-16 had been previously canceled. No claims have been amended as part of this response to the pending Office action.

The applicants respectfully request reconsideration in light of the following comments.

#### **35 U.S.C. 103 Rejection of Claims 1-4, 17-25, and 27-32**

Claim 1-4, 17-25, and 27-32 have been rejected under 35 U.S.C. 103 as being unpatentable over Houston et al, U.S. PGPub No. 2003/0139807 (hereinafter "Houston") in view of Falotico et al, U.S. Patent 7,195,640 (hereinafter "Falotico"). The applicants respectfully traverse the rejection.

Claim 1 recites:

**1.** A drug delivery device comprising: a drug; and a vascular implant having a blood-contacting surface and a helical formation on the blood contacting surface, the helical formation being capable of inducing helical flow of blood flowing past the helical formation, and the drug being releasably associated with the helical formation of the vascular implant.

The applicants respectfully submit that the present invention gives rise to a surprising technical advantage (*i.e.*, "unexpected results") which is not reported in the prior art. More specifically, the provision of the helical formation on the blood contacting surface of the drug delivery device of the present application allows the drug delivery device to hold more of the drug releasably associated with it than on a device without the helical formation. More importantly, the helical formation allows elution of more of the drug than a device without the helical formation.

Note that this surprising technical advantage is reported in the attached Rule 132 Affidavit (labeled as "Declaration"), as signed by one of the applicants.

The Office's reason for the rejection of claim 1 is based on a combination of Houston and Falotico. Yet neither document provides any suggestion of this technical advantage nor does any other motivation exist for the Office's proposed combination. In fact, Houston does not relate to drug delivery at all. And with respect to Falotico, the Office refers to column 14, lines 1 to 4 and column 18, lines 50 to 59 in which rapamycin is "directly incorporated into a polymeric matrix and sprayed onto the outer surface of the stent." Aside

from noting that "the rapamycin preferably remains on the stent for at least three days up to approximately six months, and more preferably between 7 and 30 days" (see Falotico column 14, lines 4 to 7), there is no discussion concerning the dynamics of drug delivery. There is no description of how the stent might be adapted in order to hold more of the drug or how to elute more of the drug from a stent. Furthermore, spraying a drug on the outer surface of Houston's stent would not yield the claimed invention, since Houston's stent has the helical feature on the inner surface of the stent. And there is certainly nothing in those references that would have led one skilled in the art to expect the technical advantage realized by the present invention as set out above and in the attached affidavit.

Fairly read, there is nothing about the combined teachings of Houston and Falotico that would lead to the claimed invention. In view of that, and in view of the surprising technical advantage afforded by the claimed invention, it is urged that the claimed invention non-obvious.

For these reasons, the applicants respectfully submit that the rejection of claim 1 is traversed.

Because claims 2-4, 17-25, and 27-32 depend on claim 1, the applicants respectfully submit that the rejection of them is also traversed.

### **35 U.S.C. 103 Rejection of Claim 26**

Claim 26 has been rejected under 35 U.S.C. 103 as being unpatentable over Houston in view of Falotico, further in view of Houston et al, EP 1254645A1 (hereinafter "Houston '645"). Because claim 26 is dependent upon claim 1 and because Houston '645 fails to cure the deficiency of the other prior art with respect to the rejection of claim 1, the applicants respectfully submit that the rejection of claim 26 is traversed as well.

### **Request for Reconsideration Pursuant to 37 C.F.R. 1.111**

Having responded to each and every ground for objection and rejection in the last Office action, applicants respectfully request reconsideration of the instant application pursuant to 37 CFR 1.111 and request that the Examiner allow all of the pending claims and pass the application to issue.

If there are remaining issues, the applicants respectfully request that Examiner telephone the applicants' attorney so that those issues can be resolved as quickly as possible.

Respectfully,  
Robert Gordon Hood et al.

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